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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 09/506,779 | 02/18/2000 | Dennis P. Curran | 99-038 | 7918 |

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Henry E Bartony Jr
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| EXAMINER |
|---|
| BAKER, MAURIE GARCIA |

| ART UNIT | PAPER NUMBER |
|---|---|
| 1639 | 13 |

DATE MAILED: 07/14/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

| Application No. | Applicant(s) |
|---|---|
| 09/506,779 | Curran et al |
| **Examiner** | **Art Unit** |
| Maurie G. Baker, Ph.D. | 1639 |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *THREE* MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1) ☒ Responsive to communication(s) filed on *Apr 30, 2003* .

2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

**Disposition of Claims**

4) ☒ Claim(s) *1-3, 10-16, and 45* is/are pending in the application.

4a) Of the above, claim(s) _____ is/are withdrawn from consideration.

5) ☐ Claim(s) _____ is/are allowed.

6) ☒ Claim(s) *1-3, 10-16, and 45* is/are rejected.

7) ☐ Claim(s) _____ is/are objected to.

8) ☐ Claims _____ are subject to restriction and/or election requirement.

**Application Papers**

9) ☐ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) ☐ All b) ☐ Some* c) ☐ None of:

1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____ .
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

a) ☐ The translation of the foreign language provisional application has been received.

15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____
4) ☐ Interview Summary (PTO-413) Paper No(s). _____
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

## DETAILED ACTION

1. The Response filed April 30, 2003 (Paper No. 12) is acknowledged. Claims 1, 11 and 45 were amended and no claims were cancelled or added. Therefore, claims 1-3, 10-16 and 45 are pending and under examination.

### *Status of Rejections*

2. The objection to claim 1 is withdrawn in light of the amendments made thereto. The rejection of claim 45 over Brenner is also withdrawn in light of the amendments made thereto. All other rejections are maintained. Applicant's arguments are addressed following each rejection. Note that a new rejection *necessitated by applicant's amendment* is included in this action.

### *Maintained Rejections*
### *Claim Rejections - 35 USC § 102*

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

4. The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) do not apply to the examination of this application as the application being examined was not (1) filed on or after November 29, 2000, or (2) voluntarily

published under 35 U.S.C. 122(b). Therefore, this application is examined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

5. Claims 1, 2, 10, 11, 12, 14, 15 and 45 are rejected under 35 U.S.C. 102(e) as being anticipated by Hochlowski et al (US 6,168,913) as evidenced by Webster's Dictionary (1994).

Hochlowski et al discloses "coding combinatorial chemical libraries synthesized on a plurality of solid supports by attaching "tags" that comprise fluorine containing compounds in combinations and/or ratios. The tags can be decoded while attached to the solid support by fluorine nuclear magnetic resonance spectroscopy..." (see Abstract). Various fluorine containing tags are disclosed by the reference (see column 5, line 15 through column 13, line 21); these read directly on the claimed fluorous {tagging} moieties that differ in fluorous content or structure of instant claims 2, 12 and 15.

The reference discloses using FNMR to identify the tags (see, for example, column 3, lines 2-21 and column 23, lines 1-14), creating for each solid support a code that generates "an unique FNMR spectrum" (column 4, lines 4-10). Note that for the purposes of this rejection that the term "separating" is given the art-recognized definition of "to discriminate or differentiate between", as evidenced by Webster's Dictionary. Thus, Hochlowski et al discloses "separating" the compounds of their coded libraries as the FNMR spectrum clearly *differentiates between* the tagged library members (see, for example,

column 23, lines 1-14, Example 2 and patented claims). The separation discussed above is based on differences between the FNMR chemical shifts of the tagging moieties, see column 5, line 15 through column 13, line 21 {especially column 5, line 29} and Figures. This also reads on the "differences in fluorous nature" in instant claims 1, 11 and 14 and also on the "differences between the first tagging moiety and the second tagging moiety" in instant claim 45. Lastly, as the chemical shifts of the tags are known, the "order" of separation (i.e. placement of peaks in the FNMR spectrum) to identify the compounds that are tagged is deemed to be "predetermined", as recited in instant claims 10 and 45.

***Response to Arguments***

6. Applicant's arguments filed April 30, 2003 have been fully considered but are not found persuasive. The examiner's rationale is set forth below.

7. Applicant argues that the terms "separating" or "separation" should be given a special meaning (from a chemical dictionary). Applicant has not pointed to any place in the instant specification that supports such a definition. Moreover, although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993). The examiner has given the claims their broadest reasonable interpretation and maintains that Hochlowski et al reads on the claimed invention as described in the rejection above.

8. In response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., special meaning (from a chemical dictionary) of "separating" or "separation") are not recited in the rejected claim(s). If applicant intends for "separating" or "separation" to be limited to a particular meaning, that limitation should be added to the instant claims.

9. See also MPEP 2111.01: During examination, the claims must be interpreted as broadly as their terms reasonably allow. This means that the words of the claim must be given their plain meaning unless applicant has provided a clear definition in the specification. *In re Zletz*, 893 F.2d 319, 321, 13 USPQ2d 1320, 1322 (Fed. Cir. 1989).

***Claim Rejections - 35 USC § 103***

10. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

11. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made, absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not

commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

12. Claims 1, 2, 3, 10-16 and 45 are rejected under 35 U.S.C. 103(a) as being unpatentable over Curran et al (US 5,859,247; of record) and Hochlowski et al (US 6,168,913), as set forth above.

Curran et al teach separation techniques where "organic/fluorous phase separation techniques are used to effect separations" (see Abstract). These techniques are defined in column 3, line 35 - column 4, line 4 of the reference and read on the separations of instant claims 1, 2, 11, 12, 14 and 15, especially with respect to tagging moieties that differ in fluorous content. Fluorous reversed phase chromatography is specifically described, column 3, line 49 - column 4, line 4 (reading on claims 3, 13 and 16). Curran et al teach that these methods are preferred for separations (and synthesis) of combinatorial libraries (see column 8, line 50 – column 9, line 32). The reference also teaches that a "plurality of fluorous moieties" can be used "such that any fluorous reaction components ... are separable from the target organic product" (column 6, lines 29-43) and that "it may be desirable to have more than one tag per molecule, and these tags may be the same or different" (column 16, lines 49-50).

Curran et al lacks the specific teaching of using multiple fluorous tags and separations based on differences between them.

However, the use of multiple tags in the synthesis and analysis of combinatorial libraries was well established in the art at the time of filing. For example, Hochlowski et al teaches "coding combinatorial chemical libraries synthesized on a plurality of solid supports by attaching "tags" that comprise fluorine containing compounds in combinations and/or ratios. The tags can be decoded while attached to the solid support by fluorine nuclear magnetic resonance spectroscopy..." (see Abstract). Various fluorine containing tags are taught by the reference (see column 5, line 15 through column 13, line 21); these read directly on the claimed fluorous {tagging} moieties that differ in fluorous content or structure of instant claims 2, 12 and 15.

Hochlowski et al teaches using FNMR to identify the tags (see, for example, column 3, lines 2-21 and column 23, lines 1-14), creating for each solid support a code that generates "an unique FNMR spectrum" (column 4, lines 4-10). Thus, Hochlowski et al clearly teaches differentiating between the tagged library members using their FNMR spectrum (see, for example, column 23, lines 1-14, Example 2 and patented claims). The differentiation discussed above is based on differences between the FNMR chemical shifts of the tagging moieties, see column 5, line 15 through column 13, line 21 {especially column 5, line 29} and Figures. This also reads on the "differences in fluorous nature" in instant claims 1, 11 and 14 and also on the "differences between the first tagging moiety and the second tagging moiety" in instant claim 45. Lastly, as the chemical shifts of the tags are known, the "order" of separation (i.e. placement of peaks in the

FNMR spectrum) to identify the compounds that are tagged is deemed to be "predetermined", as recited in instant claims 10 and 45.

Therefore it would have been *prima facie* obvious to one of ordinary skill in the art at the time of the invention to use multiple fluorous tags in the fluorous separations (i.e. reversed phase chromatography) of Curran et al. A person of ordinary skill in the art would have been motivated to do so based on the teachings of Hochlowski et al regarding the use of multiple fluorine containing tags in order to separate and identify each library compound (see column 2, line 65 through column 3, line 21). Also, the methodology of Curran is advantageous for combinatorial synthesis and analysis for a variety of reasons (see column 8, line 28 through column 9, line 11), such as allowing for reactions to be conducted in homogeneous phases. One would have been further motivated and had a high expectation of success because the tags of both Curran et al and Hochlowski et al are fluorine containing compounds.

***Response to Arguments***

13. Applicant's arguments filed April 30, 2003 have been fully considered but are not found persuasive. The examiner's rationale is set forth below.

14. In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections

are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.,* 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986).

15. The examiner's position with respect to Hochlowski et al is set forth above (paragraphs 7-9). Applicant argues that "Curran et al. does not disclose or suggest the tagging of multiple organic compounds with different fluorous tags" (Response, page 11). The examiner agrees, as it was stated in the rejection that "Curran et al lacks the specific teaching of using multiple fluorous tags and separations based on differences between them." The rejection is based on the *combination* of Curran et al with Hochlowski et al.

16. As stated in the rejection, the use of multiple tags in the synthesis and analysis of combinatorial libraries was well established in the art at the time of filing. For example, Hochlowski et al teaches "coding combinatorial chemical libraries synthesized on a plurality of solid supports by attaching "tags" that comprise fluorine containing compounds in combinations and/or ratios. The tags can be decoded while attached to the solid support by fluorine nuclear magnetic resonance spectroscopy..." (see Abstract). Various fluorine containing tags are taught by the reference (see column 5, line 15 through column 13, line 21); these read directly on the claimed fluorous {tagging} moieties that differ in fluorous content or structure of instant claims 2, 12 and 15. It would have been *prima facie* obvious to one of ordinary skill in the art at the time of the invention to use multiple fluorous tags in the fluorous separations (i.e. reversed phase

chromatography) of Curran et al. A person of ordinary skill in the art would have been motivated to do so based on the teachings of Hochlowski et al regarding the use of multiple fluorine containing tags in order to separate and identify each library compound (see column 2, line 65 through column 3, line 21).

***Double Patenting***

17. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

18. A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b). Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

19. Claims 1, 2, 3, 10, 11-16 and 45 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-9 of US 5,859,247 (of record) in view of Hochlowski et al (US 6,168,913).

An obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but an examined application claim not is patentably distinct from the reference claim(s) because the examined claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985).

Although the conflicting claims are not identical, they are not patentably distinct from each other because the recited claims in the patent and in the instant application encompass separations based on differences in fluorous nature. The instant method uses more than one tagging moiety, while the method of US 5,859,247 only recites one tagging moiety. However, the method instantly claimed would be obvious over that in claims 1-9 of US 5,859,247 because to use more than one tagging moiety (to aid in the separation) would be obvious to one of ordinary skill. This is demonstrated by the teachings of Hochlowski et al, which teach the differentiation of library members using a plurality of fluorine containing tags (see Abstract and column 5, line 15 through column 13, line 21).

Therefore it would have been prima facie obvious to one of ordinary skill in the art at the time of the invention to use multiple fluorous tags in the fluorous

separations of Curran et al. A person of ordinary skill in the art would have been motivated to do so based on the teachings of Hochlowski et al regarding the use of multiple fluorine containing tags in order to separate and identify each library compound (see column 2, line 65 through column 3, line 21). One would have been further motivated and had a high expectation of success because the tags of both Curran et al and Hochlowski et al are fluorine containing compounds.

***Response to Arguments***

20. Applicant's arguments filed April 30, 2003 have been fully considered but are not found persuasive. The examiner's rationale is set forth below.

21. Applicant argues that the double patenting rejection is improper for the same reasons that the rejections under 35 USC 102 and 103 are improper. The examiner respectfully disagrees for the reasons set forth in paragraphs 7-9 and 14-16.

***New Rejections – Necessitated by Amendment***
***Claim Rejections - 35 USC § 112***

22. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

23. Claim 45 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Amended claim 45 recites in step b. "the first fluorous tagging moiety being different from the first fluorous tagging so that...". This phrase is confusing and thus renders the claim indefinite.

***Status of Claims/Conclusion***

24. No claims are allowed.

25. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL.** See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

26. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Maurie Garcia Baker, Ph.D. whose telephone number is (703) 308-0065. The examiner is on an increased flextime schedule but can normally be reached on Monday-Thursday and alternate Fridays from 9:30 to 7:00.

27. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Andrew J. Wang, can be reached on (703) 306-3217. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4242. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Maurie Garcia Baker, Ph.D.
July 11, 2003

MAURIE GARCIA BAKER PH.D
PRIMARY EXAMINER